ATTACHMENT B

REMARKS

By this amendment, Applicants have provided a new set of claims 46-78 which replace the prior set of claims and which reflect the changes to the claims as discussed during a recent Interview between Applicants' representatives and the Examiner and Supervisor. In light of the fact that Applicants have now adopted the suggestions of the Examiner and Supervisor, Applicants submit that the present claims overcome the only remaining rejection to the main claim of the present application. For reasons as set forth below, Applicants submit that the present claims now clearly distinguish the present invention from the cited prior art, and that the present application is thus placed in condition for allowance.

As an initial matter, Applicants wish to express their gratitude for the Interview granted with the Examiner and Supervisor, and for the helpful suggestions made by the Examiner and Supervisor during the Interview which have greatly assisted in bringing this case to an allowance. As indicated below, Applicants have adopted the suggestions of the Examiner and Supervisor in the amended claims, and it is submitted that the suggested language now clearly distinguishes the present claims from the cited prior art.

In the prior Final Rejection, there was only a single rejection to prior Claim 1, namely that this claim was rejected under 35 U.S.C. §103(a) as being obvious in light of the Foster patent, US Patent 6,008,341. This rejection, insofar as applied to the claims as amended, is respectfully traversed for the reasons that follow.

As an initial matter, the Foster patent relates to the ClfA protein and nucleic acids coding for that protein. However, as has been acknowledged by the Examiner, the Foster patent did not disclose the preparation of a monoclonal antibody to ClfA, nor did it teach or suggest the specific epitopes which would be necessary to generate an antibody to ClfA which would have a protective effect. Accordingly, the presently claimed invention is a significant and unexpected improvement over the prior Foster patent because not only does it generate a monoclonal antibody against the ClfA protein, it indeed has been the case that the monoclonal antibody generated in accordance with the present invention has been shown to be successful in protecting against *S. aureus* infection. This has been shown in detail in Applicants' prior response, e.g., in the Declaration of Dr. Joseph M. Patti, Ph.D., and the attachments thereto, as well as in the original specification. As was shown, for example, in the Declaration of Dr. Patti and its supporting exhibits, the protective *in vivo* effect of the monoclonal antibodies of the invention was clearly demonstrated, and the successful showing of this protective effect in accordance with the invention was not only the first disclosure of any monoclonal antibody to ClfA, it was the first report of a monoclonal antibody against **any** cell surface protein from *S. aureus* that was demonstrated to give significant *in vivo* protection. Accordingly, as was discussed during the Interview between Applicants' representatives and the Examiner and Supervisor, the presently claimed invention provides significant unexpected beneficial results in a manner clearly not disclosed or suggested in any prior art reference, including the Foster patent cited by the Examiner.

Moreover, as was discussed during the Interview, it has been the case that despite the knowledge of particular target antigens, and despite the knowledge that

polyclonal antibodies may be raised to a particular antigen, it has been very difficult, if not impossible, to generate a monoclonal antibody against a particular antigen which will prove effective against infection *in vivo*. Indeed, the contrary is actually the case because there are numerous occasions wherein a suitable protective monoclonal antibody has been sought against a particular antigen, yet no commercially viable and protective monoclonal antibody has been developed despite many years of trying. As mentioned during the Interview, for example, there is still no commercially viable monoclonal antibody preparation out on the market for anti-RhD (or "anti-D") despite almost 30 years since the original anti-D antibodies were identified and utilized in polyclonal form.

Thus, despite the fact that the ClfA protein was known, and despite the fact that polyclonal antibodies to ClfA were known, the development of a protective monoclonal antibody to ClfA as in the present invention was clearly not disclosed or suggested in the prior art. In particular, the Foster patent as cited by the Examiner did not disclose or suggest such a protective monoclonal antibody, nor did it disclose or suggest which epitopes would produce protective monoclonal antibodies. Accordingly, it is clear that the present claims, which relate to monoclonal antibodies which bind to the same epitopes recognized by the specific monoclonal antibodies of the present invention, namely antibodies 12-9, 13-2, 35-220 and 35-006, are not disclosed or anywhere suggested in the prior art, and indeed afford significant unexpected benefits in terms of clinical protection as reflected in the information of record.

Applicants thus submit that independent Claim 46, which replaces prior Claim 1, is clearly not disclosed or suggested in the cited prior art, and that the Examiner's rejection on the basis of the Foster patent, insofar as applied to the new claim and its dependent claims, is respectfully traversed and should be withdrawn.

In the Official Action, the Examiner also rejected some of the dependent claims of the prior set of claims on the basis of additional references, but as noted above, these references did not bear on the patentability of the main claim of the application, Claim 1, which has now been replaced by new Claim 46 which adopted the language suggested by the Examiner and Supervisor during the recent Interview. Applicants thus submit that the additional prior art cited by the Examiner does not disclose or suggest the present set of claims and thus cannot be utilized, either singly or in combination, to anticipate or make obvious new Claim 46 or its dependent claims. Applicants thus submit that the present set of claims respectfully traverses all of the prior art rejections, and that those rejections should now be withdrawn.

In light of the amendments and arguments as set forth above, as well as the prior information of record including the previously filed Declaration of Dr. Joseph M. Patti, Ph.D., as well as other information referred to in the specification of the present application, Applicants submit that the present application overcomes all prior rejections and has been placed in condition for allowance. Such action is earnestly solicited.

END OF REMARKS